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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/660,308 | 09/10/2003 | Antonio M. Goncalves | 6056-316 CTI (189230) | 5385 |
| 23973 | 7590 | 10/25/2004 | EXAMINER | |
| DRINKER BIDDLE & REATH ONE LOGAN SQUARE 18TH AND CHERRY STREETS PHILADELPHIA, PA 19103-6996 | | | NOGUEROLA, ALEXANDER STEPHAN | |
| | | ART UNIT | | PAPER NUMBER |
| | | 1753 | | |

DATE MAILED: 10/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | | |
|----------------------------|-----------------------|--|
| Application No. | GONCALVES, ANTONIO M. | |
| 10/660,308 | | |
| Examiner ALEX NOGUEROLA | Art Unit 1753 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 July 2004.
2a) This action is **FINAL**. 2b) This action is non-final.
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-109 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) Claim(s) 2,4-14,17,18,20-41 and 46-106 is/are allowed.
6) Claim(s) 1,3,15,19,42-45 and 107-109 is/are rejected.
7) Claim(s) 16 is/are objected to.
8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
10) The drawing(s) filed on 10 September 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.
4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of July 26, 2004 does not render the application allowable.

Response to Arguments

2. Applicant's arguments filed July 26, 2004 have been fully considered but they are not persuasive.

With respect to the rejection of claims 1 and 3 as being anticipated under 35 U.S.C. 102(e) by Nakanishi Applicant asserts that Nakanishi does not disclose a substrate support. Grooves 7 and 8 in Figures 4A and 4B are clearly capable of supporting a substrate, such as gel or entangled polymer, which are commonly used in microfluidic electrophoresis devices and, more generally, capillary electrophoresis systems. See, for example, the CAPLUS abstract for "Polymeric separation media for capillary electrophoresis of nucleic acids," Sunada et al., *Electrophoresis*, 1997, 18(12-13), 2243-2254 and the abstract and col. 12, ln. 37 – col. 13, ln. 9 of Chow et al. (US 6,274,089 B1).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 43-45 and 107-109 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. No support has been found or cited for the new limitations in claims 43-45.

5. Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

- a) Claim 43: does "electrophoresis substrate" mean a body that can support an electrophoresis medium, a meaning that is used in claim 42, for example, or does it mean an electrophoresis separation medium, a meaning that is used in claim 1, for example?

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claim 42 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by the JPO abstract of Tanaka (JP 2001-1188061 A) ('Tanaka').

As a first matter, it will be noted that Applicant appears to change the meaning of "substrate" from claim to claim. In claim 1, the examiner understands "substrate" to mean separation medium. See paragraph [0013] of the specification. But in claim 42 electrophoresis "substrate" cannot mean an electrophoresis separation medium. It must mean a body used as a base or support.

Figures 1(A) and 1(B) of Tanaka are views of opposing faces of the same substrate. This is clear from the abstract and may be inferred from Figures 1(A) and 1(B). These figures show electrodes 5 through 8 that are aligned with the ends of the channels 3 and 4. Figure 2 shows a different embodiment having a cover plate. In Figure 2 either the bottom plate (3 1) alone may be construed as the substrate or the cover plate (3 2) and the bottom plate together.

The EEPROM (20) in Tanaka serves as the claimed identification device.

Alternatively, if the "electrophoresis substrate" is to be narrowly construed as an electrophoresis separation medium, Tanaka clearly discloses using electrophoresis separation medium. See Effect of the Invention in the JPO translation, which discloses that the identification device contains information about the electrophoresis substrata (gel).

8. Claim 43 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by newly cited Alam (US 5,635,045). See the abstract and Figures 1, 5, and 6.
9. Claim 43 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by newly cited Minden (US 6,342,143 B1). See the abstract and Figures 1 and 3a-d.
10. Claim 44 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by newly cited Blasband (US 5,384,025). See the abstract and Figures 3A-D and 4A and 4B.
11. Claim 44 is rejected under 35 U.S.C. 102(e) as being clearly anticipated by newly cited Anderson (US 6,485,623 B1). See the abstract and Figures 1-10.
12. Claim 45 rejected under 35 U.S.C. 102(e) as being anticipated by newly cited Anderson (US 6,163,173). See the abstract; col. 5, ll. 42-55 and col. 15, ll. 37-53. Plastics have a range of thermal conductivities.

13. Claim 45 is rejected under 35 U.S.C. 102(b) as being anticipated by newly cited Hochstrasser (US 5,773,645). See the abstract; Figures 2 and 3; and col. 4, ll. 50-63. Plastics have a range of thermal conductivities.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakanishi et al. (US 6,454,925 B1) (“Nakanishi”) in view of Soane et al. (US 6,176,962 B1) (“Soane”).

Addressing claim 1, Nakanishi teaches a cassette for use in an electrophoresis apparatus (the abstract), the cassette having an upper portion (1b) and a lower portion (1a), the cassette comprising:

at least two liquid reservoirs formed in the cassette spaced apart from one another, each reservoir being adapted to receive a liquid (buffer tanks 9 in Figure 4A);

a substrate support located between the liquid reservoirs (grooves 7 and 8);

at least one port in fluid communication with at least one of the reservoirs and extending to an external surface of the cassette (10a, 10b, 10c, and 10d);

at least one electrode located within each liquid reservoir (76); and

at least one electrical contact located on an external surface of the cassette and electrically connected to the at least one electrode so as to permit current to pass between the electrical contact and the electrode (electrodes 35a, 35b, 35c, and 35d. Also see col. 4, ll. 35-39);

wherein the upper portion includes a cover and the lower portion includes a body (Figure 4A).

Nakanishi does not mention sealing the cover to the body.

Soane discloses sealing the cover of a microfluidic electrophoresis device to the body of the same device. See the abstract; Figure 5, col. 1, ll. 51-67; and col. 2, ll. 39-57. It would have been obvious to one with ordinary skill in the art at the time the invention was made to seal the cover to the body as taught by Soane in the invention of Nakanishi because this will ensure that the well ports (10a-10d) in the cover will be properly aligned with their corresponding wells in the body and that the metallic film (14) and prism (15) will be properly aligned with detection region of the separation channel. As for the seal being substantially liquid tight, since the

channels are to be filled with liquid it would have been obvious to have the seal be liquid tight to minimize loss of sample or buffer during the analysis from spilling or evaporation.

Addressing claim 3, four liquid reservoirs and four electrodes as claimed are taught by Nakanishi (for the four liquid reservoirs note buffer tanks 9 in Figure 4A. For the four electrodes note electrodes 76). As for the claimed two ports for supplying liquid and at least one port for venting gas, note that the stated purposes for the ports are intended uses that, barring a contrary showing, do not confer any distinguishing structural features to the ports themselves; that is, a port for supplying liquid can be identical in structure to a port for venting gas, although weight will be given to the structural relationship between a port and another element of the device, such as location or position. Nakanishi teaches four ports (**10a**, **10b**, **10c**, and **10d**). Any two of the ports can be considered to be Applicant's claimed ports for supplying liquid and either of the remaining two ports can be considered to be a port for venting gas, as claimed.

17. Claims 1 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meier et al. (US 6,592,735 B1) ("Meier") in view of Serwer (US 4,693,804) ("Serwer").

Addressing claim 1, Meier teaches a cassette for use in an electrophoresis apparatus (implied the abstract, which teaches a machine configured so that an electric field can be applied

across a DNA sequencing gel), the cassette having an upper portion top support film in Figure 4) and a lower portion (bottom support film in Figure 4), the cassette comprising:

at least two liquid reservoirs formed in the cassette spaced apart from one another, each reservoir being adapted to receive a liquid (ion reservoirs shown in Figure 2);

a substrate support located between the liquid reservoirs (support film shown in Figure 4);

at least one electrode located within each liquid reservoir (platinum wire electrodes shown in Figure 2); and

at least one electrical contact located on an external surface of the cassette and electrically connected to the at least one electrode so as to permit current to pass between the electrical contact and the electrode (electrical contacts as claimed are shown, but not labeled, in Figure 2);

wherein the upper portion includes a cover (Figure 4) and the lower portion includes a body (Figure 4), the cover being attached to the body with a seal (col. 2, ll. 64-67 and col. 3, ll. 39-41).

Meier does not mention proving at least one port in fluid communication with at least one of the reservoirs and extending to an external surface of the cassette, although no covers are provided on the reservoirs, so the reservoirs have an opening in fluid communication with an external surface of the cassette.

Serwer teaches a cassette for use in electrophoresis for use in an electrophoresis apparatus (the abstract), the cassette comprising:

at least one port in fluid communication with at least one reservoir and extending to an external surface of the cassette (slots 110). The at least one port is formed by a slot in a cover over the reservoir. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide over the reservoirs a cover having a slot, which forms a port, as taught by Serwer in the invention of Meier because this will limit exposure of the buffer in the reservoirs to the atmosphere. So the chance of contaminating of the buffer will be lessened and the temperature of the buffer can be better controlled.

Meir also does not mention whether the seal is substantially liquid tight; however, since the channels are to be filled with liquid it would have been obvious to have the seal be liquid tight to minimize loss of sample or buffer during the analysis from spilling or evaporation. Seals between the reservoirs and the support would have obvious to prevent buffer leakage.

18. Claims 1, 19, 107, and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakanishi et al. (US 6,454,925 B1) ("Nakanishi") in view of newly cited Dantsker et al. (US 6,499,499 B2) ("Dantsker").

Nakanishi teaches a cassette for use in an electrophoresis apparatus (the abstract), the cassette having an upper portion (1b) and a lower portion (1a), the cassette comprising:

at least two liquid reservoirs formed in the cassette spaced apart from one another, each reservoir being adapted to receive a liquid (buffer tanks 9 in Figure 4A);
a substrate support located between the liquid reservoirs (grooves 7 and 8);

at least one port in fluid communication with at least one of the reservoirs and extending to an external surface of the cassette (10a, 10b, 10c, and 10d);
at least one electrode located within each liquid reservoir (76); and
at least one electrical contact located on an external surface of the cassette and electrically connected to the at least one electrode so as to permit current to pass between the electrical contact and the electrode (electrodes 35a, 35b, 35c, and 35d. Also see col. 4, ll. 35-39);
wherein the upper portion includes a cover and the lower portion includes a body (Figure 4A).

Nakanishi does not mention sealing the cover to the body.

Dantsker discloses sealing together layers of a microfluidic device. See the abstract; Figure 1A; and col. 6, ll. 1-24.

It would have been obvious to one with ordinary skill in the art at the time the invention was made to seal the cover to the body as taught by Dantsker in the invention of Nakanishi because this will ensure that the well ports (10a-10d) in the cover will be properly aligned with their corresponding wells in the body and that the metallic film (14) and prism (15) will be properly aligned with detection region of the separation channel. As for the seal being substantially liquid tight, since the channels are to be filled with liquid it would have been obvious to have the seal be liquid tight to minimize loss of sample or buffer during the analysis from spilling or evaporation.

As for the substrate being removably attached to the lower portion of the cassette, in effect requiring a reversible seal, Dantsker discloses a variety of sealing means including permanent, such as thermal or chemical bonds, and temporary, such as claims or screws. See

col. 6, ll. 39-47. The decision of the whether to have the layers of the device irremovably attached will depend on whether the device is to be reused or disposed after a single use. If the device is to be reused then it would be useful to have the substrate removably attached to the lower portion of the cassette to afford greater access to the microchannels for more complete cleaning.

As for the seal being an integral portion of either the body or the cover note that Dantsker discloses that the seal may be formed by chemically or thermally sealing the layers the microfluidic device. See col. 6, ll. 39-47.

As for the seal being a separate component positioned between the body and the cover, note that Dantsker discloses using single- or double-sided tape or adhesive for forming the seal. See col. 6, ll. 1-24.

Status of the Rejections pending since the Office action of March 31, 2004

19. All previous rejections are withdrawn. However, the rejections based on Nakanishi, Tanaka, Slater, Scott and the combination of Meir and Serwer have been rewritten in light of Applicant's amendment.

Allowable Subject Matter

20. Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
21. Claims 2, 4-14, 17, 18, 20-41, and 46-106 are allowed.

Final Rejection

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1753

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alex Noguerola
Primary Examiner
AU 1753
October 20, 2004